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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,277	10/20/2003	Eddie F. Ray III	4002-3433/PC545.02	2922

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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT

PAPER NUMBER

3733

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/689,277

Applicant(s)

RAY ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-35 is/are pending in the application.
- 4a) Of the above claim(s) 20-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-19 and 27-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/20/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-19 and 27-35) in the reply filed on 10/16/2006 is acknowledged.

Claims 20-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected method, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/16/2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is written as being dependent on claim 7, but there is no claim 7 present in the application. Claim 8 contains the limitation "...said housing inserter..." which first appears in claim 5. Thus, claim 8 will be considered to be dependent on claim 5 for examination purposes

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 19 is rejected under 35 U.S.C. 101 because it is drawn to non-statutory subject matter. In claim 19, lines 3-4, applicant positively recites part of a human, i.e. "...a first width transverse to the spinal column axis... a second width transverse to the spinal column axis..." Thus claim 19 includes a human within its scope and is non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8-19 and 27-35, as best understood by the examiner, are rejected under 35 U.S.C. 102(b) as being anticipated by Michelson (US Pat. 5,484,437).

Michelson discloses a spinal instrument assembly, comprising: a guide sleeve housing (Fig. 5, ref. 140 further including ref. 148) including a proximal portion (Fig. 5, portion towards ref. 148) and a distal portion (Fig. 5, portion towards ref. 102), said proximal portion including an inner wall (Fig. 5, just over ref. 101) defining a proximal chamber (Fig. 5, inside of ref 140), said housing further including a first working channel

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port (Fig. 5, ref. 154) and a second working channel port (Fig. 5, ref. 154, on opposite side of ref. 144) (column 20, lines 1-8) extending through said distal portion and in communication with said proximal chamber; and a central distractor (Fig. 5, ref. 102) in said chamber of said guide sleeve housing, said central distractor including a distractor tip (Fig. 5, near ref 102) movably positionable between said first and second working channel ports, since ref. 140 (which has in it the working channel ports) is removable and can therefor be moved independently relative to the distractor tip, said distractor tip including upper (Fig. 5, the side near ref. numeral 142) and lower distraction surfaces (Fig. 5, the side near ref. numeral 104) defining a distraction height therebetween (Fig. 5, ref. D) to maintain distraction of a spinal disc space. The proximal chamber is sized to receive a distal end of a guide sleeve. The tip of said central distractor is centrally located in said housing (Fig. 5). The central distractor is rotatable from a reduced height configuration whereby said upper and lower distraction surfaces are oriented away from vertebral endplates of a spinal disc space to a distraction configuration whereby said upper and lower distraction surfaces are oriented toward vertebral endplates of the spinal disc space, since the device could be placed at a 90 degree angle relative to the placement as shown in Fig. 5, and then could be twisted 90 degrees in order to allow the distraction surfaces to be placed as seen in Fig. 5. The guide sleeve housing is removably engageable (column 20, lines 9-15) to a housing inserter (Fig. 5, ref. 162). The central distractor includes a shaft (Fig. 5, ref. 101) extending proximally from said tip. The housing inserter and said guide sleeve housing are positionable over a proximal end of a shaft of said central distractor (Fig. 5) (column 20, lines 9-15) and

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movable therealong to position said guide sleeve housing in said operative position, since they can be detached and moved in relation to each other and can slide over each other to a degree (column 20, lines 9-15). The inner wall defines a groove therein, since the inner wall is curved and forms a channel (Fig. 5). The central distractor includes a housing engaging portion (Fig. 5, ref. 110) having an actuatable finger (Fig. 5, ref. 110) for removably engaging said groove of said guide sleeve housing. The central distractor tip includes a reduced height configuration whereby said upper and lower distraction surfaces are orientable away from vertebral endplates of a spinal disc space and said finger is not engaged to said guide sleeve housing; and said central distractor tip is rotatable to a distraction configuration from said reduced height configuration whereby said upper and lower distraction surfaces are orientable toward vertebral endplates of a spinal disc space and said finger is actuated and received in said groove thereby coupling said guide sleeve housing to said central distractor. The guide sleeve housing is removably engageable (column 20, lines 9-15) to a housing inserter (Fig. 5, ref. 162), said housing inserter having an actuatable finger (Fig. 5, ref. 160) positionable to engage said housing inserter to said guide sleeve housing. The housing inserter and said guide sleeve housing are positionable over a proximal end of a shaft of said central distractor (Fig. 5) (column 20, lines 9-15) and movable therealong to position said guide sleeve housing in said operative position, since they can be detached and moved in relation to each other and can slide over each other to a degree (column 20, lines 9-15). The central distractor is withdrawable from said guide sleeve housing (column 19, lines 55-58). The instrument further comprises a guide sleeve engageable to said proximal

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portion of said guide sleeve housing. The first working channel port and said second working channel port of said guide sleeve housing are in communication with one another through said guide sleeve housing. The guide sleeve housing includes a pair of lateral flanges extending distally therefrom on opposite lateral sides of said guide sleeve housing (Fig. 5, ref. 142). Each of said lateral flanges has a non-distracting height between upper (Fig. 5, ref. 142, the outer surface of the flange) and lower surfaces (Fig. 5, ref. 142, the inner surface of the flange) thereof. In an operative position said proximal portion of said guide sleeve housing includes a first width (Fig. 5, width across ref. 148) transverse to the spinal column axis and said distal portion includes a second width (Fig. 5, width across ref. 140) transverse to the spinal column axis, said first width being greater than said second width.

Michelson discloses a spinal surgical instrument, comprising: a shaft (Fig. 2, ref. 111); an engaging portion (Fig. 2, ref. 134) at a distal end of said shaft releasably engageable with a member (Fig. 2, ref. 128) positioned about said engaging portion; and a distractor tip (Fig. 2, refs. 126) extending distally of said engaging portion, wherein said engaging portion includes an enlarged configuration relative to said shaft and said distractor tip, since ref. 134 is wider than any portion of ref. 111 and ref. 126. The distractor tip is rotatable relative to said engaging portion, between a distraction configuration and a reduced height configuration. The distractor tip is rotatable relative to the engaging portion since the distractor tip gets screwed on to the engaging portion (Fig. 5). When being screwed onto the engaging member, one angle (e.g. 180 degrees) can be considered to be a distraction configuration and another angle (e.g. 90 degrees)

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can be considered to be a reduced height configuration. The distractor tip includes an upper distracting surface (Fig. 2, one ref. 126) and an opposite lower distracting surface (Fig. 2, the other ref. 126). At least one of said upper and lower distracting surfaces includes a vertebral endplate engaging surface (Fig. 2, the outer surface of either ref. 126). The engaging portion includes a receptacle (Fig. 2, ref. 128) and a finger movable into and out of said receptacle (Fig. 2, 116) between an engagement position (when they are screwed together) for engaging said member positioned about said engaging portion and a release position (when they are not screwed together) for releasing said member from said engaging portion. The distractor tip is rotatable relative to said engaging portion with said shaft, since they are screwed together (Fig. 5), said distractor tip being movable between a distraction configuration wherein said finger engages said member and a reduced height configuration wherein said finger is released from said member. The member is a guide sleeve housing defining first and second access ports (Fig. 2 the spaces in between ref. 126 and 120) therethrough for accessing a spinal disc space with said engaging portion removed therefrom. The guide sleeve housing includes a pair of lateral flanges (Fig. 2, both halves of ref. 128, one on either side of the rectangular slot of ref. 118) (column 18, lines 53-56) extending distally therefrom on opposite lateral sides of said guide sleeve housing. Each of said lateral flanges has a non-distracting height between upper and lower surfaces thereof (Fig. 2, the bottom surface near ref. 126, and the upper surface near ref. 128).

With regard to statements of intended use and other functional statements (e.g. ...to maintain distraction of a spinal disc space..., ...to receive a distal end of a guide

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sleeve..., ...rotatable from a reduced height configuration whereby..., ... for removably engaging said groove..., ...for accessing a spinal disc space...), they do not impose any structural limitations on the claims distinguishable over the device of Michelson which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

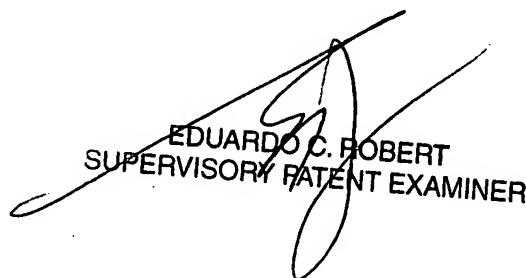
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER